

## **REMARKS/ARGUMENTS**

### **I. Summary of the Office Action Mailed September 29, 2009**

In the Office action mailed September 29, 2009, the Office asserted that the present application contains claims directed to more than a single inventive concept under PCT Rule 13.1 and accordingly required election of a single invention. The Office required Applicant to elect one of the four inventions listed below for prosecution on the merits:

- I. Group I (claims 1-5, 8 and 9): A method of diagnosing the risk of cancer in a subject
- II. Group II (claims 6 and 7): An isolated nucleic acid sequence
- III. Group III (claims 10 and 11): A peptide and an antibody having an affinity for the peptide
- IV. Group IV (claims 12 and 13): A method of treating cancer by using a siRNA

### **II. Election**

In response to the restriction requirement, the Applicant elects, with traverse, Group I. Claims 1-5, 8 and 9 read upon Group I.

As this is a US national phase of a PCT application, international unity of invention practice applies.

According to PCT Rule 13.1, the application “shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.” Under PCT Rule 13.2, unity of invention referred to in Rule 13.1 requires there be “a technical relationship among those inventions involving one or more of the same or corresponding special technical features.”

The applicant respectfully submits that PCT Rules 13.1 and 13.2 are satisfied for Groups I and II. Group I claims are directed to a diagnostic method that uses a polynucleotide of SEQ ID NO. 1 or 2 for diagnosing the presence or risk of cancer. Group II claims are directed to the polynucleotide of SEQ ID NOs. 1 and 2 used in Group I claims. Therefore, Group II claims are directed to a product and Group I claims are directed to the use of that product. Since Group I and Group II include a combination of a product and a process of use of said product the requirements of combination (2) identified by the Examiner on page 3 of the Office Action are satisfied.

The Office's attention is also drawn to part (e)(i) of Annex B ("Unity of Invention") of the administrative Instructions under the Patent Cooperation Treaty (accessible at [http://www.wipo.int/pct/en/texts/ai/annex\\_b.html](http://www.wipo.int/pct/en/texts/ai/annex_b.html), last visited October 28, 2009), which mandates including Groups I and II in the same application:

(e) **Combinations of Different Categories of Claims.** The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) *in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product....*

(Emphasis added.)

In view of the foregoing,, claims 1-9 together posses unity of invention and should be examined fully on their merits in the same application.

### III. Conclusion

Applicant respectfully requests that the restriction requirement against Groups I and II be withdrawn and all of the claims concerning Groups I and II be examined in their entirety. Should the Examiner wish to discuss this case, the Examiner is invited to call the undersigned at (312) 913-0001.

Date: October 29, 2009

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